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Predictors of Success Following Endovascular Aneurysm Repair: Mid-term Results

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Objective. *Australian cases of endovascular aneurysm repair (EVAR) performed between 1999 and 2001 have been evaluated to determine the mid-term (6 months to 5 years) safety and efficacy of the procedure. This study looks at predictors of success, based on mid-term follow-up data.*
Design of study. *This study uses results obtained from a prospective semi-voluntary register (audit) of Australian data obtained from surgeons in the private and public sector.*
Results. *Peri-operative mortality for patients enrolled in the audit was 1.8%. Ninety-three percent of procedures were technically successful (890/961). Nearly 13% of patients have had re-interventions (mostly endoluminal) at follow-up. Analysis of audit data shows that the likelihood of experiencing post-operative complications or requiring additional procedures increases with ASA rating, increasing age, large pre-operative aneurysm size, aneurysm angle* $>45°$ *and number of co-morbid conditions diagnosed.*
Conclusions. *This study confirms satisfactory mid-term results in a, national rather than unit specific, setting. Predictors of clinical failure or need for re-intervention include large aneurysm size, neck angulation* ≥ 45 *degrees and short infrarenal neck.*

Keywords: Aortic aneurysm, abdominal-surgery; Australia; Medical audit; Vascular surgical procedures.

Introduction

Following the first endovascular aneurysm repair (EVAR) by Parodi *et al*.[1] in 1991, the procedure has been enthusiastically adopted by Australian vascular surgeons, who have contributed significantly to knowledge of this procedure. The Zenith graft was developed in Perth, WA by David Hartley and Michael Lawrence-Brown and first deployed in 1993. The Royal Prince Alfred group in Sydney, NSW, led by James May and Geoffrey White performed their first procedure in 1992 and have published extensively on the procedure and outcomes of EVAR.

The Australian audit of EVAR was instigated in 1999 to consider mid to long term safety and durability. The audit has been managed by the Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S) and has been in progress for over 4 years.

This paper reviews predictors of early and mid-term success derived from statistical analysis of the audit data.

Method

ASERNIP-S is a programme of the Royal Australasian College of Surgeons (RACS) whose remit is to provide quality and timely assessments of new and emerging surgical technologies and techniques. When the audit was established, a reference group of vascular surgeons was convened to advise ASERNIP-S on clinical aspects of EVAR repair. Ethics approval for the audit was obtained from the Ethics Committee for the Royal Australasian College of Surgeons.

Operative data for patients were requested from all vascular surgeons who performed EVAR between 1st November 1999 and 16th May 2001. Follow-up for this

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Table 1. Reporting standards for technical and clinical success

	Description
Technical success	Primary technical success based on intent-to-treat basis Successful access to the arterial system using a remote site Successful deployment of the endoluminal graft with secure proximal and distal fixation Absence of death, conversion to open repair, type I or III endoleaks, or graft limb obstruction Use of additional planned components, stents, angioplasty or adjunctive surgical procedures constitutes success
Assisted primary success*	Additional unplanned endovascular procedure
Secondary technical success*	Additional unplanned surgical procedure
Clinical success	Successful deployment of device at intended location Absence of aneurysm-related death, type I or III endoleak, graft infection, thrombosis, aneurysm expansion $\geq$5 mm, aneurysm rupture, conversion to open repair, graft migration, failure of device integrity
Assisted clinical success	Additional endovascular procedures
Secondary clinical success	Additional surgical procedures

* The Australian audit data does not distinguish planned and unplanned procedures undertaken during the peri-procedural (24 h) period.

cohort of patients is continuing. The results presented here are derived from patient pre-operative, operative and follow-up information. Ongoing government funding of EVAR has been made dependent on the submission of data to the ASERNIP-S audit and over 90% of private cases performed during the audit period were submitted.

A range of pre-operative data items were collected including age, gender, co-morbidities, aneurysm diameter and morphology and pre-operative imaging. Operative information included anaesthetic techniques, type of graft, peri-operative mortality, intra-operative and post-operative complications, early endoleak and duration of post-operative hospital stay. The American Society of Anaesthesiology (ASA) classification was used to assess patient fitness for surgery. Peri-operative mortality was defined as death within 30 days of the procedure. Follow-up data collected included imaging techniques, problems identified by imaging, graft position, aneurysm size and additional procedures.

Technical and clinical success rates were calculated according to reporting standards established by the Ad Hoc Committee for standardized reporting practices in vascular surgery[2] which are summarised in Tables 1 and 2.

Statistical analyses were undertaken to answer the following questions:

Table 2. Period of technical and clinical success

	Period
Technical success	Peri- and post-operative to 24 h
Clinical success	
Initial	Up to 30 days post-operative
Short term	30 days to 6 months
Mid term	6 months to 5 years
Long term	>5 years

1. What pre- and peri-operative variables affect the likelihood of complications or re-interventions?

To answer this question, the presence or absence of complications or interventions after EVAR was regressed (logistic regression) against key predictor variables: ASA, age, AAA diameter, number of comorbidities, suitability for open repair, gender, sac size change (pre-operative and post-operative), modified 'Whites grading system[3]' (Table 3), infrarenal neck length, infrarenal neck diameter, aortic neck angle, aneurysm angle, device name and type, patient type (private or public) and smoking status. Complications included failed access, access vessel complications, failed deployment, misplaced deployment, imperfect seal, kink, and embolisation. Other complications picked up prior to discharge included device, systemic and access site complications.

2. What aneurysm morphology variables affect the likelihood of type I and II endoleaks?

Logistic regressions and unpaired *t*-tests were used to compare patients with and without endoleaks. After analysing data from the operative/discharge data sets, key predictor variables were also regressed against

Table 3. Adaptation of Whites grading scale to Australian audit data

Morphology	Extent	Points allocated
Aortic neck length	<15 mm	3
Aortic neck angulation	>45°	3
Thrombus present		3
Aortic sac angulation	>60°	3
Severe iliac artery tortuosity		3
Severe iliac artery calcification		3

No additional factors were evaluated. Following White's grading system, points were allocated as before: Grade I, 1–2 points; grade II, 3–5 points; grade III, >5 points.

whether a patient had ever had an endoleak in any of the follow-up reviews.

3. Does presence of type I or II endoleaks affect the likelihood of another procedure?

Logistic regressions and Fisher's exact test were performed to determine whether the presence of type I or II endoleaks affect the likelihood of a patient requiring another procedure.

4. What variables affect technical success and clinical success?

Regressions were performed studying relationships between technical and clinical success and key variables: ASA, age, maximum aneurysm diameter, number of diagnosed conditions, suitability for open repair, gender, sac size changes, modified 'Whites grading system, infrarenal neck length, infrarenal neck diameter, aortic neck angle, name of device, type of graft, patient type (public/private) and smoking status.

Results

A total of 961 patients who underwent EVAR were enrolled in the Australian audit. By April 2005, 27% of this group had died (263/961), and 8% were listed as lost to follow-up (75/961). Two-year or later follow-up had been received for over 90% of the remaining patients (590/623). Patients listed as lost to follow-up include those who have moved, refused follow-up, or become too frail to attend follow-up. Some patients become lost to follow-up when their surgeons retired, moved or died. During the course of the audit 82 surgeons have contributed data.

Pre-operative patient demographics and anatomical features

Most patients in the audit are male (86%, 828/961). The mean age ($\pm$SD) of patients at the time of the procedure was 75.0$\pm$6.9 years and 60% (575/961) of patients were 75 years or older. Patient fitness was measured using the American Society of Anaesthesiology (ASA) rating. Thirty-four percent of patients were listed as healthy or had only mild systemic conditions (i.e. ASA I or II). The number of systemic conditions diagnosed for patients prior to surgery ranged from 0 to more than 10 per patient (56%$\leq$3 conditions).

Mean pre-operative aneurysm diameter was 57 mm ($\pm$10.4 mm). Where maximum aneurysm diameter was reported, a total of 44% (410/933) of aneurysms measured less than 55 mm in diameter, with 27% (255/933) $\leq$50 mm in diameter. In the subset of patients whose aneurysms measured $\leq$50 mm, 20% (52/255) were women.

Ten percent (84/872) of patients had a 'neck' length less than 15 mm. Over 50% of patients had a neck diameter less than 24 mm. An infrarenal neck diameter $\geq$28 mm was recorded in 16% of cases (143/877). Significant aortic neck angulation ($\geq$45°) was noted in 13% of patients. An aneurysm angle of $\geq$60° was recorded for 1.5% of patients. Twelve percent (105/883) of patients had thrombus in the neck of the aneurysm and 22% had a saccular aneurysm (187/869).

Forty-three percent of patients (411/961) were regarded as unsuitable candidates for open repair. The main reason given was co-existent morbidity (77%, 316/411). Other reasons given included hostile abdomen, unfit for general anaesthesia and high risk of rupture. The patients who were considered fit for open repair were fitter (ASA I and ASA II 13 vs 51%, $p<0.05$) and had fewer co-morbidities (mean number 3.5 vs 2.2; $p<0.05$).

Rupture and aneurysm related deaths

Peri-operative mortality was 1.8% (17/961). A further nine patients have subsequently died with late (> 30 days) aneurysm-related deaths, bring the total of aneurysm-related deaths to 2.7% (26/961). Thirteen patients (1.4%) have had ruptured aneurysms, one died in the peri-operative period, six died late and six are surviving following treatment.

Technical and clinical success

The overall rate of technical success was 93% (890/961). It was not possible to distinguish between planned and unplanned additional endovascular and surgical procedures performed at the time of graft deployment.

Rates of clinical success are shown in Table 4. As several follow-up forms were received for each patient during the mid-term period (6 month to 5 year), clinical success was based on the most recent follow-up. However, if additional endovascular or surgical procedures had been performed (excluding conversion to open, which constitutes failure) at any time during the mid-term period then success is described as assisted or secondary. It should be noted that patients may fluctuate over time between clinical failures and successes if, for example, additional procedures have been performed, a type I endoleak

Table 4. Clinical success

	Clinical success (total)	Assisted clinical success	Secondary clinical success	Number of type 2 endoleaks with no increase in sac size
Initial success, $n=961$	89% (853)	*	*	4.6% (41)
Short term success, $n=350$	92% (321)	1.7% (6)	1.4% (5)	6.8% (24)
Mid-term success, $n=819$	91% (744)	6% (49)	1.5% (12)	4.0% (33)

* Assisted and secondary success is not shown; the questionnaire does not ask whether procedures were planned and unplanned.

disappears or the sac size changes. It should also be noted that the measure does not include deaths that are not directly attributable to the procedure (i.e. deaths occurring more than 30 days post-operatively from non-aneurysmal related causes are not considered to be clinical failures). Table 5 shows causes of mid-term clinical failure.

Endoleaks

Prior to discharge, 28/961 patients (3%) were recorded with type I endoleaks (four of whom also had type II endoleaks). A further 64/961 patients (6.5%) had type II endoleaks only. For the group of 24 patients with type I endoleaks only, 15 reported no leak at next follow-up, 3 were recorded with type II endoleaks only, 4 had additional procedures performed (one of which included a conversion to open repair following rupture), 1 patient died of septicaemia and the outcome of the last patient is unknown. For the four patients with type I and II endoleaks, two were clear at next follow-up and two had ongoing type II endoleaks only.

During mid-term follow-up, 35 patients have been diagnosed with type I endoleaks. Twenty-four required additional interventions (including three patients who were converted to open repair), six patients declined or were too frail for further intervention. The leaks resolved in three patients, however, two died following aneurysm rupture. Ten patients with type I endoleak also recorded stent migration.

Type III endoleaks were not originally specified on the questionnaire, but were added in 2003. To date only two type III endoleaks have been reported. One patient died at 24 months when an intrasac injection dislodged the contra limb. The second was diagnosed at 48 months and an extension limb was inserted endoluminally.

Table 5. Cause of mid-term clinical failure

	Mid term ($n=819$)
Increase in sac size ≥ 5 mm	25
Endoleak type II and increase in sac size ≥ 5 mm	14
Endoleak type I	8
Conversion to open	7
Migration	1
Broken wires	1

Changes in aneurysm sac size

Fig. 1 shows changes in aneurysm size over time. Aneurysms were deemed to be the same size if they were within 5 mm of the original (pre-operative) measurement. After 1 year the bulk of aneurysms are smaller then their pre-operative size, however, an increasing proportion of patients (10% at >3 years) have aneurysms that are ≥ 5 mm larger than their pre-operative size.

Additional interventions

Three types of intervention are reported:

- additional procedures performed at the time of the original procedure (often referred to as secondary procedures)
- interventions performed after the initial procedure but prior to discharge
- interventions recorded at follow-up

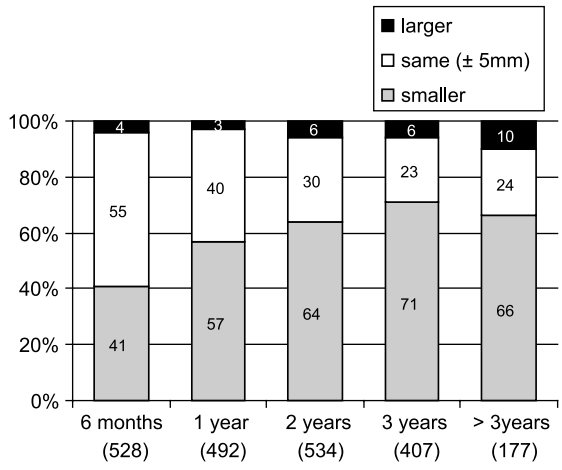

Fig. 1. Changes in aneurysm size (± 5 mm).

To date there have been 16/961 (1.7%) patients whose endoluminal repair has been converted to open repair. Of these, 10 (1.0%) had early conversions (<30 days post-operative) and 6 (0.6%) had a late conversion (11–52 months).

At the time of the procedure 24% (226/961) patients underwent an additional endovascular procedure and 4% (37/961) patients had an additional surgical procedure. An additional 1.7% of patients had endovascular interventions following the original procedure but prior to discharge (16/961), and 1.8% had surgical interventions (17/961).

Table 6 shows the number of open and endovascular interventions reported at follow-up. The number of follow-up forms received varies for each period and is highest during the first year due to increased reporting requirements during this time interval. Most interventions carried out following the original procedure were performed endoluminally.

Statistical analysis of results

1. What variables affect likelihood of complications or re-intervention following EVAR?

The risk of complications or re-interventions occurring prior to discharge is significantly (i.e. $p<0.05$) affected by a higher ASA value ($p<0.001$), high number of pre-existing comorbidities ($p<0.001$), non-suitability for open repair ($p<0.001$), older age ($p<0.001$), larger pre-operative aneurysm size ($p=0.031$) and post-EVAR increase of sac size ($p=0.036$).

The risk of complications or re-interventions occurring at follow-up is significantly affected by older age ($p<0.001$), non-suitability for open repair ($p<0.001$), higher ASA value ($p<0.001$), high number of pre-existing conditions ($p=0.001$), larger pre-operative aneurysm size ($p=0.006$) and greater aneurysm angulation ($p=0.037$).

2. What morphological variables affect the likelihood of type I or type II endoleaks?

Shorter infrarenal neck length ($p=0.012$), aortic neck angulation >45° ($p=0.026$) and larger pre-operative aneurysm diameter ($p=0.025$) significantly ($p<0.05$) affected the likelihood of type I endoleaks. Analysis showed that patients with a type I endoleak had significantly shorter neck lengths (21 mm) than those without a type I endoleak (26 mm).

Significant relationships were found between type II endoleaks and male gender ($p=0.007$), and higher ASA values ($p=0.039$). The average ASA value for those with no type II endoleaks was 2.69 and 2.85 for those with type II endoleaks.

3. Does presence of type I or type II endoleak affect the likelihood of another procedure?

As would be expected, both Fisher's test and logistic regression suggest that type I endoleaks significantly contribute to explain the variation in additional interventions. However, it also was observed that type II endoleaks significantly affect the likelihood of a patient requiring another procedure ($p<0.001$ for both tests).

4. What variables affect technical success and 30-day clinical success

Table 7 shows the factors most likely to result in technically and clinically successful repairs. An aortic neck angle of ≥45° significantly affects technical success and initial and mid-term clinical success.

Discussion

The Australian audit of endoluminal repair provides a population-based overview of mid-term outcomes

Table 6. Types of intervention reported at follow-up

	Open procedures	Endoluminal procedures
<12 months	8 patients: 9 procedures	26 patients; 28 procedures
12–24 months	6	29
24–36 months	6	23 patients; 24 procedures
>36 months	4	20

Number of follow-up forms received: <12 m=951; 12–24 m=851; 25–36 m=528; >36 m 433.

Table 7. Variables affecting clinical and technical success

	Technical success	Clinical success	
		Initial	Mid-term
Aortic neck angle (≥45)	0.008	0.047	0.007
Aneurysm diameter	0.033		
Age			0.045
Infrarenal neck length	0.027		
Modified 'White's grading system'			0.014

Statistical significance is indicated on table above, by p-values <0.05 (5%).

and predictors of success. Technical success was 92% and initial clinical success was 89%. Mid-term success is around 93%, the increased figure due to adjunctive treatment and a smaller pool of patients.

The cohort of patients entering the audit has similar demographic/pre-operative characteristics to those reported for audits elsewhere[4,5] and peri-operative mortality is very similar to that reported in the DREAM (1.2%) and EVAR-1 (1.7%) trials.[6,7] The major difference between the Australian and European audits is the type of graft used, with the Zenith graft (Cook, Australia) being used in 86% of cases performed in Australia. The Zenith graft appears to be increasingly frequently used in Europe[4] (35%, 2170/6264).

When the use of endoluminally placed grafts for the treatment of abdominal aortic aneurysms was first adopted into the repertoire of vascular surgeons, the main use mooted was for the treatment of older frailer patients who, it was deemed, would not be able to undergo the open procedure. Results from the Australian audit have shown that in many cases the treatment is being used for smaller aneurysms (i.e. $\leq$50 mm) in fitter patients (as measured by ASA).[8,9] In this paper, we have attempted to assess those factors which most affect the mid-term outcomes. Results show that the likelihood of complications or re-interventions occurring at follow-up are linked to factors such as older age, non-suitability for open repair, higher ASA values, higher number of pre-existing conditions, larger pre-operative aneurysm size and aneurysm angle of $>45°$. Apart from the larger aneurysm angle, all the other factors are those, which would incline a surgeon towards performing the procedure endoluminally. Surgeons and patients should therefore be aware, that these patients are at increased risk of requiring additional procedures or suffering complications.

The risk of developing type I endoleaks appears to be linked to shorter infrarenal neck length, aortic neck angulation $>45°$ and larger pre-operative aneurysms whilst the risk of developing type II endoleaks is affected by larger ASA values and being male. In 2001, after reviewing 238 patient records, Stanley *et al.* reported that short neck length, contour and neck diameter were the most important criteria relating to the development of endoleak.[10] Not surprisingly, the audit results also show a strong link between the presence of type I and type II endoleaks and the likelihood of another procedure. Our recommendation would be that surgeons are aware of the risk of more challenging patient morphology as a predictor of developing type I endoleaks.

Lastly, we analysed variables affecting the outcomes of technical and clinical success as defined by Chaikof *et al*.[2] The major factors resulting in technical failure were aortic neck angle $\geq 45°$, shorter infrarenal neck length and larger pre-operative aneurysm diameter. Clinical failure was driven by smaller reductions in sac size, aortic neck angles $\geq 45°$, older age and patients with higher modified 'Whites grading system' scores.

These anatomical features are clearly important in predicting those patients likely to require intervention during follow-up to maintain aneurysm sac exclusion.

The increasing proportion of patients with sac size enlarging by 5 ml or more during follow-up (10% at $>$ 3 years) reinforces the importance of regular surveillance of individuals who have undergone this procedure.

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